IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

UNITED STATES OF AMERICA,

Plaintiff,

v.

JAMES G. COLE, an individual**, JAMES G. COLE, INC.,** a corporation, and **JULIE D. GRAVES,** an individual,

Defendants.

Case No. 3:13-cv-01606-SI

ORDER OF PERMANENT INJUNCTION

Michael H. Simon, District Judge.

The Court, having considered Plaintiff's Motion for Summary Judgment and supporting documents and the entire record in this case, finds that James G. Cole, Inc. ("JGCI"), James G. Cole, and Julie D. Graves (collectively, "Defendants") violate the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 331(d), by introducing into interstate commerce unapproved new drugs, and 21 U.S.C. § 331(a), by introducing into interstate commerce misbranded drugs and adulterated dietary supplements; and finds that Defendants, unless restrained by order of this Court, will continue to violate the Act, 21 U.S.C. §§ 301-399f.

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. Plaintiff's Motion for Summary Judgment is granted.

2. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action.

3. The Complaint for Permanent Injunction states a cause of action against Defendants under the Act.

4. Defendants violate 21 U.S.C. § 331(d), by introducing or delivering for introduction, and causing to be introduced or delivered for introduction, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p) that are neither approved under 21 U.S.C. § 355(a) or (j), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

5. Defendants violate 21 U.S.C. § 331(a), by introducing or delivering for introduction, and causing to be introduced or delivered for introduction, into interstate commerce articles of drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1) in that their labeling fails to bear adequate directions for use.

6. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce articles of food (dietary supplements), as defined by 21 U.S.C. § 321(ff), that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) in that they have been prepared, packed, and held under conditions that do not meet current good manufacturing practice regulations for dietary supplements ("Dietary Supplement cGMP"). 21 C.F.R. Part 111.

7. Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (collectively, "Associated Persons"), who have received actual notice of this Order, are hereby permanently restrained and enjoined, under the provisions of 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly

manufacturing, preparing, processing, packaging, packing, labeling, holding, receiving and/or distributing any drug or food (including dietary supplement), at or from 1020 Wasco Street, Hood River, Oregon, 97031 (the "facility"), or at or from any other locations at which Defendants, now or in the future, directly or indirectly manufacture, prepare, process, package, pack, label, hold, receive and/or distribute dietary supplements, unless and until:

A. Defendants have removed all claims from their product labels, labeling, promotional materials, websites owned or controlled by or related to Defendants, and in any other media that evidence an intended use for any product as a drug within the meaning of the Act, 21 U.S.C. § 321(g);

B. Defendants retain, at Defendants' expense, an independent person or persons (the "Labeling Expert"), who is without personal, financial (other than the consulting agreement between the parties), or familial ties to Defendants and their families or affiliates, and who by reason of background, experience, education, and training is qualified to assess Defendants' compliance with the Act, to review the claims Defendants make for each of their products on all labels, labeling, promotional materials, and any internet websites owned or controlled by or related to Defendants including, but not limited to, www.maxamlabs.com and ssl.a-s-n.com. Defendants shall notify FDA in writing of the identity and qualifications of the Labeling Expert as soon as they retain such expert. At the conclusion of the Labeling Expert's review, the Labeling Expert shall prepare a written report analyzing whether Defendants are operating in compliance with the Act and in particular, certify whether Defendants have omitted all claims from each of their product labels, labeling, promotional materials, websites owned or controlled by or related to Defendants, and in any other media that evidence an intended use for any of Defendants' products causing them to be drugs within the meaning of the Act, 21 U.S.C.

§ 321(g). The report shall include the specific results of the Labeling Expert's review, including references to product names and regulations addressed in the process of conducting the review. The report shall also include copies of all materials reviewed by the Labeling Expert. The Labeling Expert shall submit this report concurrently to Defendants and FDA no later than twenty (20) calendar days after completing this review;

C. Defendants retain, at Defendants' expense, an independent person or persons (the "Dietary Supplement cGMP Expert"), who is without personal, financial (other than the consulting agreement between the parties), or familial ties to Defendants or their families, and who by reason of background, experience, education, and training is qualified to inspect Defendants' facility to determine whether the facility, methods, processes, and controls are operated and administered in conformity with Dietary Supplement cGMP, 21 C.F.R. Part 111. Defendants, if appropriate, may retain as the Dietary Supplement cGMP Expert the same independent party they retained as the Labeling Expert. Defendants shall notify FDA in writing of the identity and qualifications of the Dietary Supplement cGMP Expert as soon as they retain such expert;

D. The Dietary Supplement cGMP Expert shall perform a comprehensive inspection of Defendants' facility and the methods and controls used to manufacture, prepare, pack, label, hold, and distribute dietary supplements, and certify in writing to FDA that (1) he or she has inspected Defendants' facility, methods, processes, and controls; and (2) whether Defendants' manufacturing process is, in the Dietary Supplement cGMP Expert's opinion, in compliance with 21 U.S.C. § 342(g)(1), 21 C.F.R. Part 111, and this Order. The Dietary Supplement cGMP Expert's report of the inspection shall be submitted concurrently to Defendants and FDA no later than twenty (20) calendar days after completion of the inspection. This report shall include, but

not be limited to, the following:

(1) A determination whether Defendants' manufacturing process adequately establishes an identity specification for each component, as required by 21 C.F.R. § 111.70(b)(1);

(2) A determination whether Defendants' manufacturing process uses appropriate, scientifically valid methods for ensuring that product specifications are met, in compliance with the requirements of 21 C.F.R. § 111.75(h)(1);

(3) A determination whether Defendants' manufacturing process includes preparing and continuously following a written master manufacturing record for each unique formulation of product manufactured and each batch size, as required by 21 C.F.R. § 111.205;

(4) A determination whether Defendants' manufacturing process includes all required information in the master manufacturing record, as required by 21 C.F.R. § 111.210, including, but not limited to, the weight or measure of their products' components and dietary ingredients (21 C.F.R. § 111.210(c) and (d)); specific actions necessary to perform and verify the points, steps, or stages in the manufacturing process where control is necessary (21 C.F.R. § 111.210(h)(3)); and corrective action plans to use when specifications are not met (21 C.F.R. § 111.210(h)(5));

(5) A determination whether Defendants' manufacturing process prepares and follows a written batch production record for each unique formulation of dietary supplement manufactured, as required by 21 C.F.R. § 111.255;

(6) A determination whether Defendants' manufacturing process includes batch production records that contain all information required by 21 C.F.R. § 111.260, specifically including but not limited to a determination whether Defendants' batch production records

include:

a. the identity of equipment and processing lines used in producing the batch (111.260(b));
b. the unique identifier assigned to each component, packaging, and label used (111.260(d));
c. the actual results obtained during any monitoring operation (111.260(g));
d. the results of any testing or examination performed during the batch production (111.260(h));
e. documentation that the finished dietary supplement meets established specifications (111.260(i));
f. documentation at the time of performance for each batch that includes the date on which each step of the MMR was performed and the initials of the person performing each step (111.260(j)(1) and (j)(2));
g. documentation at the time of performance of packaging and labeling operations (111.260(k)(1) and (k)(3));
h. documentation at the time of performance of quality control (111.260(l)(2) and (l)(3));
i. documentation at the time of performance of any required material review and disposition decision (111.260(m)); and
j. documentation at the time of performance of any reprocessing (111.260(n)).

E. Should the Labeling Expert or Dietary Supplement cGMP Expert (collectively, "Experts") identify any deficiencies in their reports as described in Paragraphs 7(B) and 7(D):

(1) Defendants shall report to FDA and the Experts in writing the actions they have taken to correct all such deficiencies within thirty (30) calendar days from receiving an expert report; and

(2) The Experts shall certify in writing to FDA whether, based upon the Experts' further review and/or inspection(s), Defendants' facility and their methods, processes, and controls used to manufacture, prepare, pack, label, hold, and distribute their dietary supplement products appear to be in compliance with the Act, its implementing regulations, and this Order, and whether Defendants have omitted all claims from each of their product labels, labeling, promotional materials, websites owned or controlled by or related to Defendants, and in any other media that evidence an intended use for any of Defendants' products to be drugs within the

meaning of the Act;

F. FDA representatives inspect Defendants' facility to determine whether the requirements of this Order have been met and whether Defendants are operating in conformity with the Act, its implementing regulations, and this Order; and

G. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in Paragraphs 7(A)-(F). In no circumstance shall FDA's silence be construed as a substitute for written notification.

8. Paragraph 7 shall not apply if Defendants have in effect an approved new drug application or abbreviated new drug application filed pursuant to 21 U.S.C. §§ 355(b) or (j), and/or an investigational new drug exemption filed and in effect pursuant to 21 U.S.C. § 355(i) for all of their products, and Defendants comply with current good manufacturing practices for drugs. See 21 C.F.R. Parts 210 and 211.

9. Within fifteen (15) calendar days after the entry of this Order, Defendants, under FDA's supervision, shall destroy all drug and food (dietary supplements) products, including components of such products, that are in Defendants' possession, custody, or control. Within thirty (30) calendar days after the entry of this Order, Defendants, under FDA's supervision, shall recall and destroy all unexpired drugs and dietary supplements that were manufactured, prepared, processed, packaged, packed, labeled, held, and/or distributed prior to the date of the entry of this Order. Defendants shall bear the cost of recall, destruction, and FDA's supervision. Defendants shall not dispose of any drugs or dietary supplements in a manner contrary to the provisions of the Act, any other federal law, or the laws of any State or Territory, as defined in the Act, in which the drugs or dietary supplements are disposed.

10. After Defendants have complied with Paragraphs 7(A)-(F) and received FDA's

written notification pursuant to Paragraph 7(G), Defendants shall retain an independent person or persons who shall meet the criteria described in Paragraphs 7(B) and 7(C) to conduct audit inspections of Defendants' facility no less frequently than once every six (6) months for a period of no less than five (5) years (hereinafter, the "Auditor"). The first audit shall occur not more than six months after Defendants have received FDA's written notification pursuant to Paragraph 7(G). If Defendants choose, the Auditor may be the same person or persons retained as the Labeling Expert or Dietary Supplement cGMP Expert described in Paragraphs 7(B)-(C).

A. At the conclusion of each audit inspection, the Auditor shall prepare a detailed written audit report ("Audit Report") analyzing whether Defendants are in compliance with Dietary Supplement cGMP for their dietary supplement operations and identifying any deviations from such requirements ("Audit Report Observations").

B. Each Audit Report shall also contain a written certification that the Auditor: (1) has personally reviewed all of Defendants' product labels, labeling, promotional materials, and any and all websites owned, controlled by, or related to Defendants; and (2) personally certifies whether the product labels, labeling, promotional materials, and any and all websites owned, controlled by, or related to Defendants comply with the requirements of the Act, its regulations, and this Order.

C. As a part of every Audit Report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report observations. The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than fifteen (15) calendar days after the date the Audit Inspection is completed. In addition, Defendants shall maintain the Audit Reports in separate

files at Defendants' facility and shall promptly make the Audit Reports available to FDA upon request.

D. If an Audit Report contains any observations indicating that Defendants' drugs and/or dietary supplements are not in compliance with the Act, its implementing regulations, and/or this Order, Defendants shall, within fifteen (15) calendar days of receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of the deviations may take longer than fifteen (15) calendar days, Defendants shall, within ten (10) calendar days of receipt of the Audit Report, submit to FDA in writing a proposed schedule for completing corrections ("Audit Correction Schedule"). The Audit Correction Schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved Audit Correction Schedule.

E. Immediately upon correction, Defendants shall submit documentation of their corrections to the Auditor. Within thirty (30) calendar days after the Auditor's receipt of Defendants' documentation of corrections, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the Audit Report Observations. Within five (5) calendar days after beginning that review, the Auditor shall report in writing to FDA whether each of the Audit Report Observations has been corrected and, if not, which Audit Report Observations remain uncorrected.

11. Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons or entities in active concert or

participation with any of them are permanently restrained and enjoined from directly or indirectly doing or causing any of the following acts:

A. Violating 21 U.S.C. § 331(d), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p) that are neither approved pursuant to 21 U.S.C. § 355(a) or (j), nor exempt from approval pursuant to 21 U.S.C. § 355(i);

B. Violating 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1), or dietary supplements that are adulterated within the meaning of 21 U.S.C. § 342(g)(1); or

C. Violating 21 U.S.C. § 331(k), by causing drugs that Defendants hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1), or by causing dietary supplements that Defendants hold for sale after shipment in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1).

D. If, and for as long as, Defendant Graves ceases to be associated with, employed by, or acting on behalf of JGCI, any other dietary supplement manufacturer, or any of JGCI's or any other dietary supplement manufacturer's subsidiaries, franchises, affiliates, successors, and/or "doing business as" entities, Defendant Graves shall not be subject to the terms of this Order except as to her act(s) or failure(s) to act under this Order while associated with, employed by, or acting on behalf of JGCI, any dietary supplement manufacturer, or JGCI's or any other dietary supplement manufacturer's subsidiaries, franchises, affiliates, successors and/or "doing business as" entities.

12. If, FDA determines, based on the results of an inspection, a review of Defendants'

products, product labels, labeling, promotional materials, or websites owned or controlled by or related to Defendants, a report prepared by Defendants' Experts or the Auditor, or any other information, that that Defendants have violated the Act or its implementing regulations, have failed to comply with any provision of this Order, or that additional corrective actions are necessary to achieve compliance with the Act, applicable regulations, and/or this Order, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease manufacturing, processing, packing, labeling, holding, promoting, and/or distributing any or all drugs and/or dietary supplements;

B. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Order;

C. Submit additional reports or information to FDA as requested;

D. Pay liquidated damages as provided in Paragraph 20 below;

E. Recall any article(s) at Defendants' expense; or

F. Take any other corrective action(s) as FDA, in its discretion, deems necessary to bring Defendants and their products into compliance with the Act, applicable regulations, and/or this Order.

This remedy shall be separate and apart from, and in addition to, any other remedy available to the United States under this Order or under the law.

13. Upon receipt of any order issued by FDA pursuant to Paragraph 12, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or

other action described in Paragraph 12 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the Act, its implementing regulations, and this Order and that Defendants may resume operations. The cost of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in Paragraph 12 shall be borne by Defendants at the rates specified in Paragraph 16.

14. Within ten (10) calendar days after FDA's request for any labels, labeling, promotional materials, and/or downloaded copies (on CD-ROM) of any websites owned and/or controlled by or related to Defendants, Defendants shall submit a copy of the requested materials to FDA at the address specified in Paragraph 19. Within ten (10) calendar days from the acquisition of any websites owned and/or controlled by or related to Defendants, Defendants shall submit a copy of all website content and the website address to FDA at the address specified in Paragraph 19.

15. FDA representatives shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facility and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Order. During such inspections, FDA representatives shall be permitted immediate access to buildings, equipment, in-process and finished materials, containers, labeling and other materials therein; to take photographs and make video recordings; to take samples of Defendants' finished and unfinished materials and products, containers, labels, labeling, and other promotional materials; and to examine and copy all records relating to the receipt, manufacture, processing, packing, labeling, promoting, holding, and distribution of any and all of Defendants' products. The inspections shall be permitted upon presentation of a copy of this Order and appropriate

credentials. The inspection authority granted by this Order is separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

16. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses specified in this Order or that FDA deems necessary to evaluate Defendants' compliance with this Order. For the purposes of this Order, inspections include FDA's review and analysis of Defendants' claims contained in product labels, labeling, promotional materials, and any and all websites owned or controlled by or related to Defendants. The costs of such inspections shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Order is signed by the parties, these rates are: $88.45 per hour and fraction thereof per representative for inspection work; $106.03 per hour or fraction thereof per representative for analytical or review work; $0.56 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

17. Within ten (10) calendar days after the entry of this Order, Defendants shall provide a copy of this Order, by personal service or certified mail (restricted delivery, return receipt requested), to each and all of his Associated Persons, shall post the Order on all websites under Defendants' control, and shall ensure that the Order remains posted at each location for as long as the Order remains in effect. Within thirty (30) calendar days after the entry of this Order, Defendants shall provide to FDA an affidavit of compliance, stating the fact and manner of

compliance with the provisions of this Paragraph and identifying the names and positions of all Associated Persons who have received a copy of this Order and the manner of notification. In the event that Defendants become associated, at any time after the entry of this Order, with new Associated Persons, Defendants shall: (a) within fifteen (15) calendar days of such association, provide a copy of this Order to each such Associated Person by personal service or certified mail (restricted delivery, return receipt requested), and (b) on a quarterly basis, notify FDA in writing when, how, and to whom the Order was provided.

18. Defendants shall notify FDA, in writing, at the address specified in Paragraph 19, at least fifteen (15) calendar days before any change in ownership, character, or name of its business, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, franchises, affiliates, or "doing business as" entities, or any other change in JGCI's corporate structure, or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Order. Defendants shall provide a copy of this Order to any potential successor or assignee at least fifteen (15) calendar days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this Paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

19. All notifications, certifications, reports, correspondence, and other communications to FDA required by this Order shall be addressed to the Director, Seattle District Office, United States Food and Drug Administration, 22215 26th Avenue SE, Suite 210, Bothell, Washington, 98021.

20. If Defendants fail to comply with the Act, its implementing regulations, and/or any provision of this Order, including any time frame imposed by this Order, Defendants shall

pay to the United States of America: (a) ten thousand dollars ($10,000) in liquidated damages for each violation of the Act, its implementing regulations, and/or this Order; (b) an additional three thousand dollars ($3,000) in liquidated damages per day, per violation, for each violation of the Act, its implementing regulations, and/or this Order; and (c) an additional sum in liquidated damages equal to twice the retail value of any distributed drugs or dietary supplements that are adulterated, misbranded, or otherwise in violation of the Act, its implementing regulations, and/or this Order. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Order or the law.

21. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Order, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees, investigational expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and administrative court costs relating to such contempt proceedings.

22. All decisions specified in this Order shall be vested in the discretion of FDA and shall be final. If contested, FDA's decisions under this Order shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

23. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Order and for the purpose of granting such additional relief as may be necessary or appropriate.

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The Court hereby directs entry of this Order of Permanent Injunction.

IT IS SO ORDERED.

DATED this 5th day of February, 2015.

/s/ Michael H. Simon
Michael H. Simon
United States District Judge